510(K) SUMMARY

510(k) Number: K130983

SEP 26 2013

Date Prepared: September 20, 2013

Submitter Information

Submitter: Genii Inc. Street Address: 2145 Woodlane Drive Suite 101-W St. Paul, MN 55125 Establishment registration: Fee paid awaiting Registration Number	Contact Person: Marcia Morris Phone: 651-501-4810 Email: marcia.morris@genii-gi.com

Device Information

Trade Name	Genii ArC Smart™ Argon Probe
Common Name	Argon Coagulation Probe
Classification Name	Electrosurgical, Cutting & coagulation & Accessories
Regulation /Product Code	21 CFR 878.4400
Product Code	GEI
Regulatory Classification:	Class II
Device Panel:	General & Plastic Surgery

The Genii ArC Smart™ Argon Probe is substantially equivalent to the previously-cleared.

ConMed Endoscopic Technologies, ConMed Beamer Argon Probe, K081644.

Predicate Device

Predicate Device	Manufacturer	FDA 510(k)
ConMed Beamer Argon Probe	ConMed Endoscopic Technologies	K081644

DEVICE DESCRIPTION

The Genii ArC Smart™ Argon Probe is a flexible, single patient use catheter accessory which delivers argon gas and energy for non-contact coagulation therapy in conjunction with an argon equipped electrosurgery generator such as the Genii ***gi4000***. It is intended for flexible endoscopic applications.

The Genii ArC Smart™ Argon Probe consists of a hollow polytetrafluroethylene (PTFE) tube containing a stainless steel wire that extends from a probe connector to the distal end of the probe. The proximal end of the stainless steel wire is crimped into the connector body. The distal end of the wire is crimped to an electrode made of tungsten in a configuration specifically

designed to enhance the ionization of argon gas as the gas passes through the open lumen of the PTFE tube. The electrode remains recessed in the PTFE tube such that there is no direct tissue contact during the electrosurgery procedure.

The ArC Smart™ Probe is fabricated in several sizes (2.3mm to 3.2 mm outer diameters; 220 to 330cm lengths) to accommodate the various sizes of flexible endoscopes used by a physician performing various argon assisted coagulation procedures. The devices accommodate an argon flow rate of 0.1 to 2.0 liters per minute over all probe sizes. The clinical use maximum is 90 watts.

The ArC Smart™ argon probes are shipped sterile in sealed Tyvek pouches and are single use only. Sterilization is by ethylene oxide.

INTENDED USE/INDICATIONS FOR USE (IFU)

The Genii ArC Smart™ Argon Probe is a flexible probe indicated for use in argon enhanced coagulation of tissue.

A copy of the IFU statement is included with each box of sterile probes. The full IFU is provided in Section 13.0 Proposed Labeling

SUMMARY OF TECHNICAL INFORMATION

The Genii ArC Smart™ Argon Probe consists of a hollow PTFE tube containing a stainless steel wire that extends from a probe connector to the distal end of the probe. The proximal end of the stainless steel wire is crimped into the connector body. The distal end of the wire is crimped to an electrode made of tungsten in a configuration designed to enhance the ionization of argon gas passing through the open lumen of the PTFE tube. The electrode remains recessed in the PTFE tube such that there is no tissue contact during a procedure. The device is a flexible, single patient use catheter and wire designed to deliver both argon gas and high frequency energy to allow production of agas plasma and provide non-contact hemostasis and tissue ablation.

The sizes and product numbers of the ArC Smart™ argon probes are:
G11-400-01 2.3mm outer diameter X 220cm length
G11-400-02 2.3mm outer diameter X 330cm length
G11-400-03 3.2mm outer diamers X 220cm length

SUBSTANTIAL EQUIVALENCE

Mfg/Device	Electrode material	Tubing material	Wire material	Single use	Shipped Sterile	Flow rate range (all sizes)*	Clinical use watt range (all sizes)*
Genii/ArC Smart™ argon probe	Tungsten	PTFE	Stainless steel	Yes	Yes	0.1 to 2.0 l/min	20-90
ConMed Beamer™ argon probe	Tungsten	PTFE	Stainless steel	Yes	Yes	.3 to 1.0 l/min	20-60

The Genii ArC Smart Probes and the predicate ConMed Beamer Argon Probes (K081644) are both offered in comparable sizes suitable for their identical intended use. Both devices are flexible, single patient use catheters and wire designed to deliver both argon gas and high frequency energy to allow production of gas plasma and provide non-contact hemostasis and tissue ablation. Both are used in identical clinical applications and patient populations. They are used with similar gas flow and watt settings in clinical flexible endoscopic applications. Both devices are transported, stored and used under similar environmental conditions. Both are used with argon capable electrosurgery generators as the energy source.

In addition, both devices are composed of identical materials, are single use and shipped sterile. The tungsten electrode design of both devices are virtually identical. With the ArC Smart™ probe, the electrode remains recessed in the PTFE tube such that there is no tissue contact during a procedure. For the Conmed predicate, a ceramic tip extends beyond the tip of the electrode to prevent tissue contact during coagulation. The ArC Smart™ catheter color is white, while the Conmed is green. Minor feature differences such as probe catheter color and tip style do not raise any new questions regarding safety or effectiveness of the device when used as labeled.

Both devices perform as intended. Evidence of comparable performance is provided in two ex vivo tissue studies, over three tissue types. Testing showed no significant differences.

SUMMARY OF TESTING

Biocompatibility – Biocompatibility test were performed as follows;

- MEM Extraction Cytotoxicity Assay Using L-929 – ISO 10993
- Intracutaneous Reactivity Test - ISO 1099

Performance, Standards and Bench Tests – The following testing was performed;

- EN 60601 -1 Medical electrical equipment Part 1: General requirements for safety.
- IEC 60601-2-2, Medical electrical equipment Part 2: Particular requirements for the safety of high frequency surgical equipment.
- IEC 60601-2-18 Edition 3.0. Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- Two Ex Vivo tissue tests using three tissue types comparing zones of coagulation at comparable watt settings, flow rates and application times.

CONCLUSIONS

The Genii ArC Smart™ argon probe has identical indications for use as the predicate device and essentially identical technological characteristics. Minor feature differences do not raise any questions regarding safety or effectiveness of the device. The Genii ArC Smart™ argon probe performs as intended, and presents no unacceptable risks to the intended patient population or end user. Genii ArC Smart™ argon probe is substantially equivalent to the predicate device (K081644).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Genii Incorporated
% Mr. Tracy Eberly
Regulatory Affairs/Quality Assurance Specialist
3640 Pillsbury Avenue
Minneapolis, Minnesota 55409

September 26, 2013

Re: K130983
Trade/Device Name: Genii ArC Smart™ Argon Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 5, 2013
Received: August 7, 2013

Dear Mr. Eberly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) number K130983

Device Name: Genii ArC Smart™ Argon Probe

Indications for Use:

The ArC Smart™ Argon Probe is indicated for argon enhanced coagulation of tissue.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003649036
Date: 2013.09.25 11:27:03 -04'00'

(Division Sign -off) for MXM
Division of Surgical Devices
510(k) Number: K130983